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THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. Z. COSMETICA USA, LLC, a company, and PHILIP J. ZELLNER, ARON I. PODELL, and ROBERTA PODELL individuals, Defendants.	Civil No. CV-06-2467 (LDW) CONSENT DECREE FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, commenced this action by filing its Complaint for Permanent Injunction on the 19th day of May 2006, against Z. Cosmetica USA, LLC ("Z. Cosmetica" or "the firm"), a company, and Philip J. Zellner, President, Aron I. Podell, former Vice President of Operations, and Roberta Podell, former Head of Quality Assurance/Quality Control, individuals.

Defendants, Aron I. Podell and Roberta Podell, without admitting or denying the allegations of the Complaint, have appeared and consented to the entry of this Decree without contest and before any testimony was taken, and the United States of America, has consented to this Decree, as it pertains to defendants, Aron I. Podell and Roberta Podell.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over Aron I. Podell and Roberta Podell.

2. The Complaint for Permanent Injunction states a cause of action against Aron I. Podell and Roberta Podell under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97 ("the Act").

3. The government has alleged that Aron I. Podell and Roberta Podell violate the Act, 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

4. The government has alleged that Aron I. Podell and Roberta Podell violate the Act, 21 U.S.C. § 331(k), by causing drugs, within the meaning of 21 U.S.C. § 321(g)(1), that they hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

5. The government has alleged that Aron I. Podell and Roberta Podell violate the Act, 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs, within the meaning of

21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. §§ 352(c), (f)(1), (f)(2), i(3), and (o).

6. The government has alleged that Aron I. Podell and Roberta Podell violate the Act, 21 U.S.C. § 331(k), by causing drugs, within the meaning of 21 U.S.C. § 321(g)(1), that they hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(c), (f)(1), (f)(2), i(3), and (o).

7. The government has alleged that Aron I. Podell and Roberta Podell violate the Act, 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs, within the meaning of 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

8. Aron I. Podell and Roberta Podell represent to the government and the Court that, as of January 13, 2006 and February 10, 2006, Aron I. Podell and Roberta Podell, respectively, are no longer employed by Z. Cosmetica and are no longer engaged in manufacturing, preparing, processing, packing, repacking, labeling, holding, distributing, and/or causing the introduction into interstate commerce of any articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), either at or from Z.

Cosmetica's facility at 1650 New Highway Farmingdale, New York 11735 or any other facility owned or operated by Z. Cosmetica.

9. Upon entry of this Decree, Aron I. Podell and Roberta Podell are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered into interstate commerce drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k), by causing drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered into interstate commerce drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352;

D. Violating 21 U.S.C. § 331(k), by causing drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are held for sale after shipment of one or more of their components in

interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352;

E. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs, within the meaning of 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to pursuant to 21 U.S.C. § 355(i).

10. Within thirty (30) calendar days after entry of this Decree, and every twelve (12) months thereafter, defendants, Aron I. Podell and Roberta Podell shall submit to FDA in writing the name, address, and, where applicable, the FDA registration number of each firm, individual, entity, facility, or location at or from which they are employed or otherwise engaged in causing drugs to be manufactured, prepared, processed, packed, repacked, labeled, held, distributed, and/or introduced into interstate commerce, as well as the dates on which defendants were or are employed or engaged in the foregoing activities.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, or any other information, that corrective actions are necessary for Aron I. Podell and Roberta Podell to achieve compliance with the Act or this Decree, FDA may, as and when it deems necessary, order Aron I. Podell and/or Roberta Podell in writing to take appropriate

action, including, but not limited to, one or more of the following:

A. Cease any and all participation in the manufacturing, preparing, processing, packing, repacking, labeling, holding, distributing, and/or causing the introduction into interstate commerce of any or all drug(s); or

B. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring the activities of Aron I. Podell and/or Roberta Podell into compliance with the Act or this Decree.

12. Any cessation described in paragraph 11(A) shall continue until FDA notifies Aron I. Podell and/or Roberta Podell in writing that they appear to be in compliance with the Act and the requirements of this Decree, and that they may, therefore, resume their participation in manufacturing, preparing, processing, packing, repacking, labeling, holding, distributing drugs, and/or causing drugs to be introduced into interstate commerce.

13. Within ten (10) calendar days after the entry of this Decree, Aron I. Podell and Roberta Podell shall provide a copy of this Decree, by personal service or registered mail, to each and all of their employers who are engaged in causing drugs to be manufactured, prepared, processed, packed, repacked, labeled, held, distributed, and/or introduced into interstate commerce.

Within thirty (30) calendar days of the date of entry of this Decree, Aron I. Podell and Roberta Podell shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

14. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the District Director, New York District Office, United States Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433.

15. Should the United States bring, and prevail in, a contempt action against Aron I. Podell and/or Roberta Podell to enforce the terms of this Decree, Aron I. Podell and/or Roberta Podell agree to pay attorney fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

16. Aron I. Podell and Roberta Podell shall abide by all decisions of FDA, which decisions shall be final. FDA decisions under this Decree shall be reviewed by the Court, if necessary, under the arbitrary and capricious standard, set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be conducted without any

discovery by either party and shall be based exclusively on the written record before FDA at the time the decision was made.

17. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED:

Dated this 14th day of AUGUST, 2006.

UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

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Roberta Podell
Former Head of Quality Assurance/
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